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The challenge of framing for efforts to mitigate the risks of "dual use" research in the life sciences

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ABSTRACT

Drawing upon insights from research in the social sciences about the role of "issue framing" in policy debates, the paper presents an argument for employing "Responsible Science" as the fundamental frame for strategies to engage scientists and scientific organizations in issues related to the potential risks posed by "dual use" research in the life sciences. It argues that this focus on *responsibilities* rather than *requirements* will be more effective, particularly in initial engagement efforts. The work of several international scientific organizations to employ this framing in their education and outreach activities is presented to illustrate the advantages of such an approach. The paper also includes a case study of a controversy over dual use research with highly pathogenic avian influenza to illustrate the power of framing in policy debates.

1. Introduction

Remarkable advances in the life sciences hold the promise of solutions to the world's growing health, food, and energy challenges, as well as the benefits of a new bio-economy. But the developments are also sparking a range of ethical, social and legal concerns, including that the knowledge, tools, and techniques resulting from these discoveries could be used to produce new bioweapons or enable bioterrorism. In the security realm, the scope and pace of the advances potentially pose fundamental challenges to the national and international institutions and policies that have been developed to prevent the misuse of the life sciences to cause deliberate harm.

The present international security landscape combines a strong norm against the misuse of the life sciences to cause deliberate harm with a weak institutional regime to prevent such actions. The cornerstone of the international regime, the 1972 Biological and Toxin Weapons Convention (BWC), has no agreed mechanisms to verify compliance with its prohibitions or to act against violations of its terms. The BWC's 8th review conference in November 2016 failed to agree on new, positive measures or even the continuation of its annual meetings of experts, highlighting concerns about the future of international efforts at biological nonproliferation and disarmament (Mackby, 2017; BWC, 2017). Although salvaged with agreement on a new set of experts meetings in December 2017, the concerns remain.

As the formal political process around the BWC unfolds over the next several years, filling any gaps and promoting constructive action will likely continue to rest on achieving a "web of prevention" as an active strategy.[2] The argument for the web concept is that multiple organizations and arrangements at the national, regional, and international level are relevant to the task of fostering and sustaining biosecurity. Beyond governments, a wide and varied array of nongovernmental stakeholders are essential elements of a

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[2] The International Committee of the Red Cross popularized the term as part of its 2002 appeal, *Biotechnology, Weapons, and Humanity*. See also Rappert and MacLeish (2014).

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successful prevention strategy, including industry, the public health community, the law enforcement and security communities, and so on. The web's effectiveness, however, depends on engaging the active support of stakeholders for policies and actions where their contributions are most relevant. This paper focuses on the efforts to engage the scientific community, both individual scientists and scientific organizations, in preventing and mitigating the particular risks associated with the potential misuse of research.

Mobilizing the scientific community in support of biological nonproliferation and disarmament faces a number of challenges. One is the scope of research about which policy makers should be concerned. In 2003, a report from the U.S. National Academy of Sciences coined the phrase "dual use dilemma" to describe the risk that research intended for benign purposes could also be misused to develop biological weapons or for bioterrorism (NRC, 2004).[3] The members of the committee that produced the Fink report, named for the committee's chair, Gerald Fink of MIT, could not have anticipated that "dual use research" would become the standard term for a set of the security issues raised by modern biotechnology. But although in common use, it remains controversial. Critics argue in particular that the concept is too broad to be useful and could lead to policies that unnecessarily hamper important research. In 2007, when the U.S. National Science Advisory Board for Biosecurity (NSABB) proposed a framework for oversight of dual use research, the Board argued that

> Because arguably most life sciences research has some potential for dual use, the NSABB strove to delineate a threshold that would identify that subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security. This subset of research is referred to herein as "dual use research of concern" (NSABB, 2007: 16).

U.S. policy has primarily focused on this narrower category of dual use research of concern or DURC for the last decade.[4]

The Fink report also illustrated dual use risks with the example of seven classes of experiments that the authoring committee considered plausible potential microbial threats. The committee argued that the potential risks extended well beyond advances in microbiology,[5] but policy in the United States and overseas has continued to concentrate on this field of life sciences research.[6] This reflects the history of past biological weapons programmes that weaponized human, plants, and animal disease causing agents, and the international norm embodied by the BWC is thus traditionally described as preventing "the use of disease as a weapon."[7]; But it also affects how ongoing policy debates and efforts to engage scientists are framed.

"Framing" refers to a set of sometimes overlapping concepts and theoretical perspectives, developed in a number of social science fields, which provide insights into how individuals, groups, and societies perceive, organize, and communicate about reality. "Framing effects refer to behavioral or attitudinal outcomes that are not due to differences in *what* is being communicated, but rather to variations in *how* a given piece of information is being presented (or framed) in public discourse" (Scheufele and Iyengar, 2014: 1). "Competing interests frame issues in ways that strategically advantage their political positions, emphasizing certain aspects of an issue over other considerations, influencing estimations of the causes, consequences, and solutions to a policy problem" (Nisbet and Lewenstein, 2002: 5). Efforts to create a compelling frame that defines an issue in policy debates over emerging technologies are thus often a key feature of the strategies used by different groups. One can think of examples such as "Frankenfoods" in the battles over genetically modified organisms in agriculture or the current competing frames of "autonomous weapons systems" versus "killer robots." Studies of communication provide insights into how to design and convey information and messages to enhance the chances of understanding and acceptance by the recipients, including for emerging technologies (Nisbet & Lewenstein, 2002; Scheufele & Lewenstein, 2005). The understanding and application of insights about framing is central to the emerging "science of science communication" (Jameison, Kahan, & Scheufele, 2017). The next section offers an example of how what I call "competing catastrophes" came to frame the controversy over research with pathogens with pandemic potential. This is followed by an example of how some international scientific organizations have framed scientists' engagement in biosecurity issues as part of the "responsible conduct of research" or the larger "social responsibility of science."

[3] This is different from the traditional concept of "dual use" in security, which refers largely to technology and products that, although intended for commercial purposes, may have military applications. There are traditional dual use commercial items in biotechnology, such fermenters, that may be subject to controls, and the ready availability of these items via the internet is a subject of proliferation concern (see, for example, Zilinskas, 2015). Controls may also extend to "intangible technology," which comes closest to the Fink Committee's concept of "dual use." According to the U.S. State Department, this "includes, but is not limited to, instructions (written or recorded), working knowledge, design drawings, models, operational manuals, skills training, and parts catalogues" (https://www.state.gov/strategictrade/practices/c43180.htm).

[4] The current U.S. government definition of DURC is "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security" (U.S. Government, 2012: 1–2).

[5] "The seven areas of concern listed here only address potential microbial threats. Of course, modern biological research is much broader, encompassing all of the health sciences, agriculture, and veterinary science. It also includes diverse industries such as those that manufacture pharmaceuticals, cosmetics (e.g., Botox), and soft drinks (e.g., citric acid production). Moreover, all of these areas are changing rapidly. The great diversity as well as the pace of change makes it imprudent to project the potential both for good and ill too broadly and too far into the future. Therefore, the Committee has initially limited its concerns to cover those possibilities that represent a plausible danger and has tried to avoid improbable scenarios. Over time, however, the Committee believes that it will be necessary not only to expand the experiments of concern to cover a significantly wider range of potential threats to humans, animals or crops but also to include oversight of work conducted for or performed within the private sector as well as non-NIH [National Institutes of Health] government facilities and sponsored activities that are not already voluntarily complying with the Guidelines [recommended in the report]" (NRC, 2004: 114).

[6] The seven types of experiments covered by the 2012 U.S. policy for DURC, are essentially the same as those in the Fink report.

[7] For a history of past weapons programmes, see Wheelis et al. (2006). More recently advances in fields such as neuroscience, in genome editing tools such as gene drives, and the growth of a global "bioeconomy" that relies on biotechnology-based production methods are expanding the range of security concerns (see, for example, Dando (2015), National Academies of Sciences, Engineering, & Medicine (2016a), and Royal Society (2015)). These new issues are not yet widely reflected in policy.

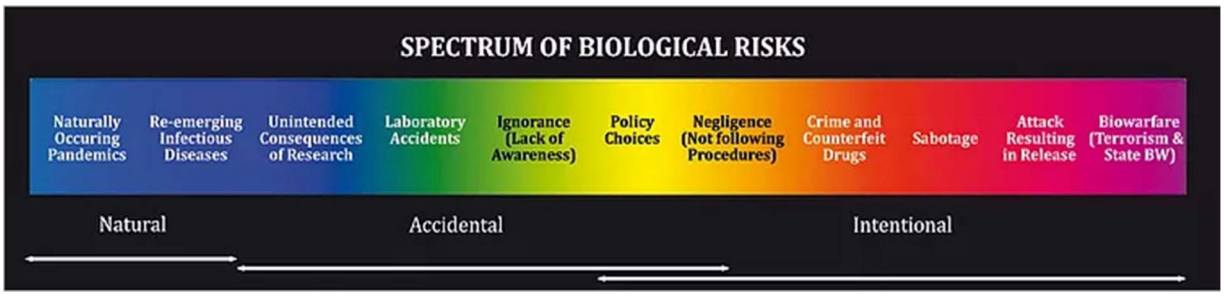

Fig. 1. Spectrum of Biological Risks.
Source: International Council for the Life Sciences.

2. Competing catastrophes and research with pathogens with pandemic potential

Fig. 1 illustrates a widely cited portrayal of the spectrum of sources of biological risks, from the specter of naturally occurring pandemics at one extreme to biological warfare by states or terrorists at the other. Both ends represent low probability, but high consequence events. The original purpose of the graphic was to convey a range of risks, and it is often used to encourage an audience to think about how policies to address one set of risks could help ameliorate others. The current emphasis on "health security," in which increasing global capacity to prevent and combat infectious disease outbreaks provides important capabilities that could be deployed in the event of a deliberately caused disease outbreak is a good example. The Global Health Security Agenda, launched in 2014, acknowledges the essential need for a multilateral and multi-sectoral approach to strengthen both global and national capacity to prevent, detect, and respond to infectious disease threats whether naturally occurring, deliberate, or accidental. Once established, the capacity would mitigate the devastating effects of Ebola, MERS, other highly pathogenic infectious diseases, and bioterrorism events."[8]

The figure can also be used to present a more zero-sum view of the risks, however. Could efforts to prevent one catastrophe increase the risks of another? For example, could policies to limit some areas of dual use research out of security concerns hamper vital efforts to prevent or respond to potential pandemics? "Nature is the best bioterrorist" is a common riposte to anyone arguing for the need to pay attention to risks from dual use research or sometimes even biological weapons or bioterrorism. Millions of casualties each year from naturally occurring infectious diseases offer a graphic contrast to the lack of any bioterrorist incidents since the anthrax letter attacks of 2001, which are sometimes presented as a "biocrime." And it should be noted that the continuing lack of consensus within the security community about the nature, likelihood, and severity of the risks from state and non-state actors compounds the problem of crafting and presenting a compelling alternative frame.[9] An example of this zero-sum competing catastrophes argument is illustrated by the ongoing controversy over research with pathogens with the potential to cause pandemics.

What became known as the "gain-of-function" (GOF) controversy emerged in late 2011.[10] It began when influenza researchers in the United States and the Netherlands funded by the U.S. National Institutes of Health (NIH) submitted manuscripts with the results of experiments with highly pathogenic H5N1 avian influenza to *Nature* and *Science*. Influenza is widely considered to pose the greatest threat of a devastating global outbreak and the H5N1 strain is one of the flu strains considered to have pandemic potential. So the researchers set out to explore the conditions under which the virus might become transmissible among mammals.

> Using well-known techniques, the groups had selected for influenza strains highly transmissible between ferrets [the human model for influenza research], identified and sequenced the strains' genetic mutations, inserted the mutated genes into a new virus, and, by observing the behavior of the newly constructed viruses, demonstrated a causal link between the mutated genes and degree of transmissibility between mammals (NRC, 2013: 1).

However, reviewers flagged the manuscripts as raising biosecurity concerns because the experiments could also provide knowledge to those who would use the results to cause deliberate harm. The journals sought the advice of the NSABB, which had been consulted about several potentially problematic publications since its creation in 2004.[11]

When the NSABB initially recommended against publication unless certain details were omitted from the methods section in December 2011, a storm of controversy erupted. One of the key features of the debate over the merits of the research was that there were vocal scientists on both sides of the argument; this was not simply the science community aligned against the government as was more typical of such publication controversies in the past.[12]

The initial phases of the controversy played out over the next few months. In January 2012, a group of influenza researchers

[8] See https://www.ghsagenda.org/about.
[9] See, for example, Watson et al. (2017) for the results of a Delphi study involving biosecurity experts in the United States.
[10] This account is drawn largely from the reports of three workshops on the controversy held by the National Academies of Sciences, Engineering, and Medicine between 2012 and 2016 (NRC, 2013; NRC, 2015; NASEM, 2016b). Other references are included to provide sources of additional information about various points in the controversy.
[11] See NASEM (2017a: 18–20) for a list of the papers and the results of the NSABB reviews.
[12] A number of previous cases are discussed in NRC (2004) and NASEM (2017a).

announced a 2-month moratorium on H5N1 research that could produce new highly pathogenic, highly transmissible strains to allow time for an international debate on the issues (Enserink, 2012). In February the World Health Organization (WHO) brought together a small group of public health and influenza experts. WHO was a natural international convener because it oversees a global network of collaborating research centers on influenza as well as the international process to identify the candidates for annual flu vaccines. In addition, national limits on influenza research in the name of security could disrupt the painstakingly negotiated Pandemic Influenza Preparedness Framework (PIP) adopted by the World Health Assembly in May 2011.[13] But critics of the research argued that this also gave WHO a major stake in the outcome of the controversy, which raised questions about its capacity to be a neutral forum. The group's recommendation to publish the manuscripts in full once concerns about biosecurity and appropriate communication of the results were addressed confirmed the expectations of both advocates and critics. Editorials in major newspapers such as one in the *New York Times* headlined "An Engineered Doomsday" reflected the intensity of the public controversy (New York Times, 2012).

The NSABB met again in late March and, based on further discussion, the presentation of additional information by the authors and other experts, and the statement by NIH that it did not have a legal basis to demand redaction, the Board voted (unanimously for one paper and by a majority vote for the other) to recommend publication in full of revised versions of the manuscripts. Both papers were published soon thereafter. In addition, on March 29 the U.S. government released a new *Policy for Oversight of Life Sciences Dual Use Research of Concern*. The policy set out an agreement among all 15 federal agencies supporting life sciences research to establish regular reviews of their portfolios for work involving 15 specific agents and toxins and 7 categories of experiments. As part of the review, the agency would "Assess the risks and benefits of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk [and] based on the risk assessment, in collaboration with the institution or researcher, develop a risk mitigation plan to apply any necessary and appropriate risk mitigation measures" (U.S. Government, 2012: 3). A subsequent policy, to provide guidelines for the responsibilities of research-performing institutions receiving federal funds for DURC research, took effect in September 2014 (U.S. Government, 2014).

In addition to the engagement of the WHO, the controversy had other international dimensions. Because one of the researchers, Ron Fouchier, was based in the Netherlands, the Dutch government also became involved. It decided that, under European Union regulations aimed at preventing the proliferation of weapons of mass destruction (WMD), submitting the paper to *Science* constituted an "export" and Professor Fouchier should have applied for a license in advance. Under protest, Fouchier applied for a license, which was approved, but he also appealed the ruling. A Dutch court upheld the ruling in 2013, and the Dutch government continues to view exports controls, along with an extensive programme of outreach to the research community, as the appropriate method for addressing concerns about publication of dual use research (Enserink, 2013).[14]

After the United States government issued its DURC policy and the two research papers were published, the controversy continued to simmer at a lower level as new research with highly pathogenic avian influenza periodically raised concerns. In Europe, for example, the Fouchier case raised serious questions at the national and regional level about whether the European Union might decide that its measures against weapons of mass destruction (WMD) should apply to all member states and become engaged in more active oversight. The European scientific community expressed widely different views to the European Commission in the second half of 2013 about the relative risks and benefits of such research. The European Society for Virology wrote to the head of the European Commission (EC) in October to raise concerns about the damage to important research that would result if it became subject to export controls. In December, another group of scientists wrote an opposing letter through the Foundation for Vaccine Research to highlight what it saw as the safety and security risks associated with the research (NASEM, 2016b: 54–55). (Although the controversy began over security concerns, the potential biosafety risks of an accidental release from a laboratory soon became equally important in the debates.) The divisions within the scientific community led the EC and its chief scientific advisor to request a study from the European Academies Scientific Advisory Council (EASAC) in 2014 in search of common ground (EASAC, 2015). Leaders of both camps were represented on the committee for the consensus study, giving its recommendations particular weight.

In addition, the German government asked the German Ethics Council to review whether the current legal framework as well as existing codes of conduct in the academic and private sectors were adequate to support decisions about funding for such research. The Council's Opinion made a series of recommendations, ranging from proposals for individual researchers and the scientific community to proposals for funding bodies, legislators, and international initiatives (German Ethics Council, 2014: 179). At present, a series of voluntary measures are being implemented under the leadership of the German National Academy of Sciences Leopoldina and the German Research Foundation, but the potential for future legislative action remains as an incentive for the German scientific community to take the issues seriously.[15]

The debates continued into 2014 and a series of significant biosafety lapses at U.S. government laboratories spurred different groups of scientists to organize to provide a collective expression of their views about the implications for what had now become

[13] The PIP's goals are to maintain "a dynamic, equitable balance between sharing influenza viruses that have pandemic potential, and distributing the benefits that result" (http://www.who.int/influenza/pip/WHO_PIP_brochure.pdf?ua=1). Further information may be found at http://www.who.int/influenza/pip/en/; accessed January 27, 2018.

[14] The Dutch government also asked the Royal Netherlands Academy of Arts and Sciences (KNAW) to review and update the code of conduct for biosecurity it had prepared earlier at the government's request and make recommendations for future policy. See van der Bruggen (2015) and KNAW (2013) for further information.

[15] "The Joint Committee on the Handling of Security-Relevant Research was established by the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG). The goal of the committee is to support research institutions in the sustainable implementation of the recommendations published in June 2014 by DFG and the Leopoldina under the title 'Scientific Freedom and Scientific Responsibility'" (https://www.leopoldina.org/en/about-us/cooperations/joint-committee-dual-use/). See the website for further information.

known as "gain-of-function" (GOF) research.[16] One group, called the Cambridge Working Group after its founding meeting at Harvard University, issued a consensus statement in July focused solely on biosafety concerns that recommended

> For any experiment, the expected net benefits should outweigh the risks. Experiments involving the creation of potential pandemic pathogens should be curtailed until there has been a quantitative, objective and credible assessment of the risks, potential benefits, and opportunities for risk mitigation, as well as comparison against safer experimental approaches. A modern version of the Asilomar process, which engaged scientists in proposing rules to manage research on recombinant DNA, could be a starting point to identify the best approaches to achieve the global public health goals of defeating pandemic disease and assuring the highest level of safety. Whenever possible, safer approaches should be pursued in preference to any approach that risks an accidental pandemic (Cambridge Working Group, 2014).

This statement was soon followed by a competing statement from another new group, Scientists for Science, which argued

> Scientists for Science are confident that biomedical research on potentially dangerous pathogens can be performed safely and is essential for a comprehensive understanding of microbial disease pathogenesis, prevention and treatment. The results of such research are often unanticipated and accrue over time; therefore, risk-benefit analyses are difficult to assess accurately.
>
> If we expect to continue to improve our understanding of how microorganisms cause disease we cannot avoid working with potentially dangerous pathogens. In recognition of this need, significant resources have been invested globally to build and operate BSL-3 and BSL-4 facilities, and to mitigate risk in a variety of ways, involving regulatory requirements, facility engineering and training. Ensuring that these facilities operate safely and are staffed effectively so that risk is minimized is our most important line of defence, as opposed to limiting the types of experiments that are done (Scientists for Science, 2014).

The groups gathered signatures and sought press coverage for their views. Individual scientists also spoke out, and although a number of scientists signed both statements, the signs of polarization within the community grew.

On October 16, 2014, the United States again became the center of attention in the controversy. The White House announced the launch of a "deliberative process" to assess the risks and benefits of some GOF experiments. To the surprise of those beyond the interagency decision-makers, the scope of the process was extended beyond highly pathogenic H5N1 avian influenza to include Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). This was the first time these viruses had figured in the discussions. The most controversial part of the deliberative process, which the White House expected to last less than one year, was the decision to institute a federal funding "pause" in parallel to the other elements.

> New USG funding will not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity (White House, 2014a: 2).[17]

The deliberations would have a number of components. The NSABB was charged to "(1) advise on the design, development, and conduct of risk and benefit assessment studies" and "(2) provide recommendations to the USG [sic] on a conceptual approach to the evaluation of proposed GOF studies" (NRC, 2015: 2–3). The National Institutes of Health, which funded almost all the research subject to the process and oversaw the NSABB, would commission the formal assessment of the potential risks and benefits; the assessment would be carried out by private contractors. The NSABB also commissioned an analysis of the ethical issues associated with GOF research from bioethicist Michael Selgelid. The National Academies of Sciences, Engineering, and Medicine (NASEM) were requested to "provide a forum for broad public debate, which will inform the NSABB's deliberations and the development of USG [sic] policy on GOF research" (NRC, 2015: 3). The forum would consist of two public conferences with international participation. "The first conference would offer the opportunity for input from a wide range of stakeholders about both general principles that should guide the assessments of benefits and risks and what specific issues should be considered, while the second would provide an opportunity for comments on the NSABB's draft policy recommendations once the assessments were completed (NRC, 2015: 3).

The first public symposium by the National Academies was held in December 2014, but after that the process slowed down (NRC, 2015). The NSABB produced its framework to guide the formal risk and benefit assessments in May 2015 (NSABB, 2015a), which was carried out by Gryphon Scientific. The draft risk and benefit assessments (Gryphon Scientific, 2015),[18] along with the Selgelid paper

[16] As the NSABB noted, "Recently, the phrase "gain-of-function research" has become synonymous with certain studies that enhance the ability of pathogens to cause disease. However, gain-of-function studies, as well as loss-of-function studies, are common in molecular microbiology and are essential to understanding molecular pathogenesis of infectious diseases. Changes to the genome of an organism, whether naturally occurring or directed through experimental manipulations in the laboratory, can result in altered phenotypes, as biological functions are lost or gained. Investigators routinely conduct loss- and gain-of-function experiments to understand the complex nature of host-pathogen interactions that underlie transmission, infection, and pathogenesis" (NSABB, 2016: 5). Employing the more general term also had the effect of engaging a wider swath of the virology community who now became concerned that proposals to limit research would expand beyond the narrow focus on highly pathogenic avian influenza.

[17] The pause applied only to certain experiments within a broader grant or contract, and an appeals process allowed that "an exception from the funding pause may be granted by the head of the federal funding department or agency if that official determines in writing that the research is urgently necessary to protect public health or national security" (White House, 2014b: 5). NIH initially identified 18 experiments as likely to be subject to the pause; the number eventually rose to 21, of which 10 received exemptions.

[18] The Gryphon Scientific draft and final reports, along with substantial additional material, are available at http://www.gryphonscientific.com/gain-of-function/

(Selgelid, 2015) and the NSABB's draft recommendations (NSABB, 2015b), were released in December 2015 and discussed at an NSABB meeting in January 2016.[19] The second Academies symposium was held in March (NASEM, 2016b) and the final NSABB recommendations were produced in May 2016 and provided to the interagency process (NSABB, 2016). The NSABB recommended a process that put substantial emphasis on reviews and decisions early in the life cycle of research, and, like the broader U.S. policy for DURC, allowed for monitoring and adjustments to any risk mitigation plans if unexpected results emerged. One of the NSABB's findings was "There are life sciences research studies, including possibly some GOF research of concern, that should not be conducted because the potential risks associated with the study are not justified by the potential benefits" (NSABB, 2016: 2).

By this point, the deliberative process had stretched toward two years. Once the interagency process began, there were no further public discussions by the government. On January 17, 2017, the White House Office of Science and Technology Policy released its *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*. "The Guidance recommends consistent and appropriate Federal agency review and reporting processes for the oversight of Federally funded research that is anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPP)" (White House, 2017: 1). Federal agencies that adopted a review mechanism consistent with the recommendations in the *Guidance* would fulfill the necessary conditions to end the funding pause. On December 19, 2017, more than three years after the deliberative process began, the Department of Health and Human Services announced its review mechanism and later that day NIH announced that the funding pause was lifted (NIH, 2017). A few of the headlines that followed the announcement – "NIH lifts 3-year ban on funding risky virus studies" in *Science* (Kaiser, 2017) or "NIH Lifts Ban On Research That Could Make Deadly Viruses Even Worse" on National Public Radio (Greenfieldboyce, 2017) – suggest the controversy over this and other forms of dual use research is far from over.

3. A proposed framing to address the challenges

Against this backdrop of controversy and division among parts of the life sciences community, this paper argues that what is needed is a way to frame biological risks that can address the controversies, or at least make them more manageable. The irony is that this controversy among some scientists is accompanied by a widespread lack of awareness among most life sciences researchers. Even a long-running dispute like the gain-of-function debates, or the imposition of polices such as the U.S. review procedures for DURC has not led to a significant increase in awareness in the United States (NASEM, 2017a) and the situation seems to be true in other parts of the world.[20]

For those interested in making security issues an accepted feature of discussions about the implications of developments in life sciences research, a successful framing of the problem would have a number of characteristics. It would facilitate engaging many stakeholders and fit within the mandates of governments and relevant international organizations. In particular, it would enable reaching the broadest possible array of scientists in settings ranging from academia to industry to public health and beyond. At the same time, it would be compatible with engaging specialized groups of scientists working on more security-relevant activities such as research in high containment laboratories. Finally, such a framing would complement existing legal and regulatory structures and provide a basis for discussing potential changes in research practices or additional security measures.

As discussed further below, a number of organizations and actors argue for framing security issues related to the life science within a broader context of "Responsible Science" and utilize it in their outreach efforts. Potential risks of dual use research are framed as one part of the general social responsibility of science, along with other ethical issues. Note that this puts the initial emphasis on *responsibilities* rather than legal *obligations*, which is the more natural focus of the security community.

There are a number of arguments to support a Responsible Science framing. This approach provides the opportunity to build on the existing culture of responsibility in the life sciences (and science more generally). The current culture is certainly imperfect, but the international scientific community is giving increasing attention to improving and expanding it. This presents a moment of opportunity for including issues related to dual use research. The current attention reflects the increasingly global nature of life sciences research and capacity, which is increasing the need to build common standards and practices to facilitate growing international collaboration (IAC-IAP, 2012). It also reflects the need to respond to conspicuous cases of ethical lapses (NASEM, 2017b). The effort is also genuinely international, which offers significant advantages in the world of international policy.

The current culture includes broad norms of science in service to humanity, including the public that supports continued funding for research. Discussions of responsible conduct of research are part of the larger question of the social responsibilities of science, which puts an emphasis on what scientists "should" do, rather than what they "must." Increasingly, scientists are considered to be responsible for more than simply doing the very best science. This view was a major theme in a 2012 report from the IAC-IAP, *Responsible Conduct in the Global Research Enterprise:*

> Because of the increasing importance of research in the broader society, scientists and other scholars bear a responsibility for how research is conducted and how the results of research are used. They cannot assume that they work in a domain isolated from the needs and concerns of the broader world (IAC-IAP, 2012: x).

Over the last decade there have been a number of important statements from international scientific organizations reflecting the recognition that scientific freedom is not absolute and that researchers also bear important responsibilities. Names do matter as part of framing and a striking example comes from the International Council for Science (ICSU), for decades one of the staunchest

[19] The draft papers, along with archived webcasts of the discussions at the NSABB meeting, may be found at https://osp.od.nih.gov/biotechnology/nsabb-meetings/.

[20] The first and most systematic attempt to document the level of awareness internationally was the series of seminars conducted by Malcolm Dando and Brian Rappert. For further information, see Rappert and MacLeish (2014).

Box 1
Examples of Statements and Reports Addressing the Social Responsibilities of Science and a Broader Definition of Responsible Conduct of Research.

- IAP (2014). *Statement on Realising Global Potential in Synthetic Biology: Scientific Opportunities and Good Governance.* http://www.interacademies.net/10878/Scientific_Opportunities_and_Good_Governance.aspx
- ICSU Committee on Freedom and Responsibility in the Conduct of Science (2014). *Freedom, Responsibility and Universality of Science*. https://www.icsu.org/cms/2017/04/CFRS-brochure-2014.pdf. (formerly the ICSU Committee on Freedom in the Conduct of Science).
- IAP/IAC (2012). *Responsible Conduct in the Global Research Enterprise*. http://www.interacademies.org/Publications/33362.aspx
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advocates for the principles of unfettered scientific freedom.

> To address and promote both aspects [freedom and responsibility], ICSU established the Committee on Freedom and Responsibility in the conduct of Science (CFRS) in 2006. This Committee differs significantly from its predecessors that, since 1963, had focused on scientific freedom, in that it is explicitly charged with also emphasizing scientific responsibilities (ICSU, 2014: 3).

A list of international statements and reports that make some form of this argument for a broader conception of scientific responsibilities, including some already cited, may be found in Box 1.

There are also significant traditions of self-governance in the life sciences, sometimes as independent initiatives such as some of the continuing efforts related to dual use issues, and also in conjunction with government guidelines or other “soft law” measures. It is important to note, as a 2015 report from the European Academies Scientific Advisory Council recognized, that “self-regulation means that there are checks and balances on research agreed within the scientific community and does not mean that each researcher is free to decide for themselves what procedures to follow” (EASAC, 2015: 17).

Within a number of life sciences fields of particular interest for biosecurity, biosafety norms and practices are central components of a culture of responsibility.[21] More generally, various types of codes set out basic standards of responsible behavior.

- *Codes of ethics:* Aspirational codes that aim to set realistic or idealistic standards as well as alert individuals to certain issues;
- *Codes of conduct:* Educational or advisory codes that aim to provide guidelines for action, raise awareness of issues, and foster moral agency;
- *Codes of practice:* Enforceable codes that prescribe or proscribe certain behavior (Rappert, 2004: 2).

A second argument in favor of the Responsible Science framing is that *it makes scientists part of the solution, not part of the problem.* This is particularly important for dual use issues. If researchers have undertaken their work for the benefit of humankind, what is the relevance for them of security or the national and international measures to promote it? Rejection or resentment is a plausible response to the suggestion that their research could pose security risks, particularly if it means additional administrative costs or requirements for a problem they may not recognize or accept as a legitimate concern.

Scientists and scientific organizations hold important keys to building and sustaining the prevailing scientific culture (NASEM, 2017b), and some are already contributing to an extension of the existing culture to include biosecurity. One example is the InterAcademy Partnership (IAP), a network of 130 academies of science and medicine.[22] According to the IAP website

> Just as each academy has the potential to represent an authoritative voice nationally, this unified voice of academies aims to have

[21] See, for example, the analysis and recommendations of the (U.S.) Federal Experts Security Advisory Panel (FESAP, 2015) after a series of serious biosafety lapses at U.S. government laboratories.

[22] Founded in 1993 and expanded and re-launched in 2016, the InterAcademy Partnership (IAP) is a global partnership of more than 130 merit-based national and regional academies of science, engineering, and health, which aims to maximize the contributions of science toward understanding and solving the world's most challenging problems. Through this structure, IAP and its members are active in countries that constitute 95 percent of the world's population. Building on the extensive track record of independent, evidence-based advice delivered by its member organizations over the past two decades, IAP projects include statements, reports and convening activities, with the aim of providing knowledge and sound advice to governments and international organizations. Further informaiton is available at http://www.interacademies.org/

great impact at the international level. IAP provides a collective mechanism and voice for science academies to further strengthen their crucial roles as providers of evidence-based policy and advice at both national and international levels (IAP, 2017).

When the IAP, then known as the InterAcademy Panel on International Issues, became engaged in biosecurity issues in 2004, it provided an opportunity to add the voice of the science community at a time when most of the voices arguing that biosecurity and dual use research should be treated as a significant policy issue were coming from governments and international security organizations. IAP mobilized its member academies to establish a Biosecurity Working Group. The Working Group's original membership has grown to include the national academies of Australia, China, Cuba, Egypt, India, Nigeria, Pakistan, Poland, Russia, the United Kingdom and the United States. Over the years the Working Group has engaged with international organizations, in particular the BWC, to highlight the implications of trends in science and technology for the Convention and international security more broadly, and to support outreach and education projects to promote attention to biosecurity. Other national academies have also carried out important work. All of the IAP activities employ the Responsible Science framing.

A few examples will illustrate the range of IAP's work and its application of Responsible Science, beginning with its 2005 *Statement on Biosecurity* that provided principles to guide science bodies while preparing codes of conduct. A major motivation for the Statement was the opportunity presented by the decision to devote the 2005 BWC intersessional agenda to "the content, promulgation, and adoption of codes of conduct for scientists" (IAP, 2005). That year's meetings of Experts and States Parties provided an important opportunity to engage scientific organizations in the work of the BWC, and a number of national academies have since been involved in developing their own codes, sometimes with the encouragement of their national governments. Another statement, this one on *Realising Global Potential in Synthetic Biology: Scientific Opportunities and Good Governance* in 2014 concluded that "Maintaining biosecurity brings challenges beyond those of biosafety: for biosecurity the core defence rests on the responsibility of the scientific community" (IAP, 2014).

As mentioned above, the IAP's most ambitious efforts to date are its 2012 report *Responsible Conduct in the Global Research Enterprise* and a companion educational handbook, *Doing Global Science*, released in 2016. The report explicitly frames scientists' responsibilities to address the risks of misuse as part of broader responsible conduct of science

> Science and other forms of scholarship have been incredibly productive by seeking knowledge unfettered by tradition, ideology, and external pressure. At the same time, research can have a profound influence on the environment, human health and well-being, economic development, national security, and many other facets of human life. Many areas of science and technology can be used for destructive as well as constructive purposes, and researchers have a special responsibility to understand and address issues of "dual use." Research on biological pathogens, for example, poses both risks and benefits for human health (IAC-IAP, 2012:15).

The report concluded that "Researchers should bear in mind the possible consequences of their work, including harmful consequences, in planning research projects," and included a discussion of biosecurity as a key example of scientists' responsibility to help prevent the misuse of their research (IAC-IAP, 2012: 16).

Doing Global Science is intended to help a range of audiences explore the dimensions of responsible conduct, including the "values that should inform the responsible conduct of scientific research in today's global setting" (IAP, 2016). Like the parent report, the handbook addresses biosecurity and offers a variety of resources for those who wish to delve further into the issues.

Increasing the inclusion of biosecurity as part of a broader recognition of the social responsibility of science within the scientific community and its leading organizations is only one part of the effort. Policy makers and the security community also need to accept Responsible Science as a legitimate framing for their activities. As mentioned above, this is not the immediately obvious choice. Not surprisingly, members of the security community and diplomats who inhabit the world of international treaties are more inclined to frame their engagement strategies on the legal requirements with which individuals and institutions must comply. The final report of the 6th BWC Review Conference in 2006, for example, urged

> …the inclusion in medical, scientific and military educational materials and programmes of information on the Convention and the 1925 Geneva Protocol. The Conference urges States Parties to promote the development of training and education programmes for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as of the obligations of States Parties under the Convention (BWC, 2006: 11).

The Weapons of Mass Destruction Directorate of the U.S. Federal Bureau of Investigation has framed its outreach to the life sciences community as "Security Protecting Science," in this case from insider threats and others with nefarious intent.

Over the past decade, however, there have been growing signs of acceptance for a Responsible Science framing, particularly as a way to conduct initial engagement that can reach a wide audience and then lead to more security-focused efforts as appropriate depending on the nature of a scientist's or an institution's research. In the BWC, the report of 2013 BWC Meeting of States Parties included the conclusion that

> "In order to further efforts on education and awareness-raising about risks and benefits of life sciences and biotechnology, States Parties agreed on the value of using science responsibly as an overarching theme to enable parallel outreach efforts across interrelated scientific disciplines…" (BWC, 2013: 8)

The final report of the 8th BWC review conference included the statement that as part of their national implementation measures, States Parties should "encourage the promotion of a culture of responsibility amongst relevant national professionals and the

voluntary development, adoption and promulgation of codes of conduct" (BWC, 2016: 12).

Responsible Science is also finding footholds beyond the BWC. One of the five deliverables for the Biological Security sub-Working Group of the Global Partnership for the Prevention of Weapons of Mass Destruction, a coalition of some 30 countries that seeks to fund and coordinate projects and activities in the areas of chemical, biological, nuclear and radiological security, is "Reduce proliferation risks through the advancement and promotion of safe and responsible conduct in the biological sciences" (U.S. Department of State, 2012). In October 2013 the UK government chose "Responsible Science" as the theme for one of the Global Partnership meeting under its presidency, and added a public session on the topic held at the Royal Society (UK Foreign & Commonwealth Office, 2013). And although those outside government using the Responsible Science framing prefer to talk about "enhancing" or "building on" an existing culture, the 2013 Nobel Peace Prize Lecture by Ambassador Ahmet Üzümcü, Director-General of the Organization for the Prohibition of Chemical Weapons also deserves mention

> Our aim is to contribute to efforts towards fostering a culture of responsible science. This will ensure that current and future generations of scientists understand – and respect – the impact that their work can have on security (OPCW, 2013)

The signs of acceptance from both the scientific and policy side suggest that taking a less traditional approach to framing dual use issues to engage a key sector in biological nonproliferation and disarmament can gain traction among both scientists and the policy community.

The change reflects a growing recognition that compliance with legal obligations is a necessary but not sufficient condition to fully address the potential risks of dual use research in the life sciences. This is part of a wider effort to move beyond a "check-the-boxes" mentality of adherence to regulations to active engagement in addressing risks.[23] The remarks by Ambassador Üzümcü about "promoting a culture of responsibility" () and the recommendations of the Federal Experts Security Advisory Panel in the United States (FESAP, 2015) are examples. Responsible Science offers a constructive alternative to the zero-sum competing catastrophes frame that supports this broader approach.

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